

# Safe Handling of Engineered Nanoparticles: Emerging Consensus Standards

Center for Occupational and Environmental Health & The Molecular Foundry

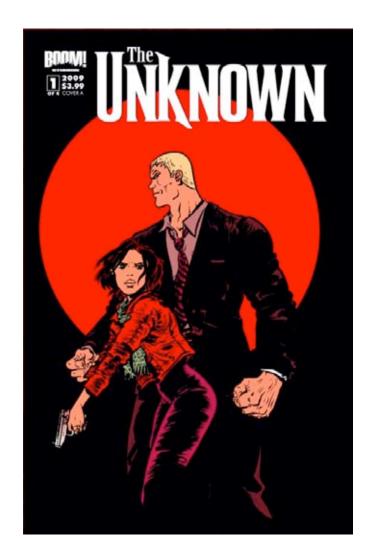
July 29, 2009

Rick Kelly, MS, CIH
Lawrence Berkeley National Laboratory

#### 2004: How Do You Protect People When...



- You don't understand the toxicology
- You don't know how well PPE is going to work
- You don't know what health effects to expect
- You don't really know which routes of exposure are important
- You don't know how to measure exposure
- You don't know how to do medical surveillance
- There are no regulations or consensus standards
- The first NIOSH sponsored Nano EH&S conference hasn't been held yet!



#### **2004 University of California Guidelines**



- University of California issues draft guidelines on the safe handling of nanomaterials
  - —Use basic good laboratory practices
  - —Don't forget hazards of precursors
  - —User respirators if handling nanopowders outside of a hood
  - —Exhaust synthetic equipment to the outside
  - —Manage contaminated equipment
  - —Nothing on exposure assessment
  - —Nothing specific on waste
  - —No requirement to filter effluent



## Department of Energy Policy Statement 9/15/05



## U.S. Department of Energy Washington, D.C.

POLICY

**DOE P 456.1** 

9-15-05

**SUBJECT:** SECRETARIAL POLICY STATEMENT ON NANOSCALE SAFETY

- Adopt, as appropriate, national consensus standards as they emerge
- Use existing EH&S control systems
- Monitor research developments and react accordingly
- DOE says it will support ongoing research and policy making



## NIOSH Publishes First Draft Approach Document 10/1/05



This information is distributed solely for the purpose of pre dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by CDC/NIOSH and should not be construed to represent any agency determination or policy.

Approaches to Safe Nanotechnology

An Information Exchange with NIOSH

National Institute for Occupational Safety and Health Centers for Disease Control and Prevention

October 1, 2005

## NIOSH Publishes First Draft Approach Document 10/1/05



- Raise Awareness of the issue
- Provide interim recommendations
- Facilitate information exchange
- Identify Information gaps
- Respond to the many inquiries they were receiving



## NIOSH Publishes First Draft Approach Document 10/1/05



- Air Monitoring—"...uncertain as to what measurement technique should be used to monitor exposures in the workplace."
- Engineered Controls—"...control of airborne exposure to nanoparticles...engineering control techniques similar to those used in reducing exposures to aerosols."
- Work Practices—"The incorporation of good work practices
  ...can help to minimize worker exposure..."
- Protective Clothing—"Currently, no guidelines are available on the selection of clothing ...for the prevention of dermal exposure..."
- Respirators—"Since nanoparticles are typically smaller than 100 nm they are theoretically collected more efficiently than the 0.3 µm test aerosols." (HEPA filtration and respirators)
- Spill Cleanup—"No specific guidance is currently available on the cleaning up of nanomaterials spills."

  National Institute for Occupational Safety and Health

## **EPA Publishes First Draft** "White Paper" 1/2/05





December 2, 2005 External Review Draft

#### U.S. Environmental Protection Agency

EXTERNAL REVIEW DRAFT

Nanotechnology White Paper

Prepared for the U.S. Environmental Protection Agency by members of the Nanotechnology Workgroup, a group of EPA's Science Policy Council

Science Policy Council
U.S. Environmental Protection Agency
Washington, DC 20460

#### NOTICE

This document is an external review draft. It has not been formally released by the U.S. Environmental Protection Agency and should not at this stage be construed to represent Agency position.

- General review of the issues, nothing that can be used in the field
- Required 25 months to finalize



### 2005 DOE NSRC Approach Document

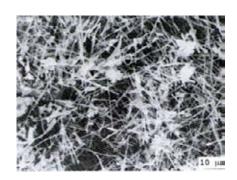


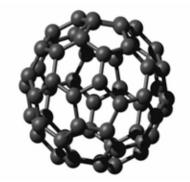


#### **Purpose and Limitations**



- Provide <u>guidance</u> to the five NSRCs for the development of safety controls
  - —Not intended to be adopted verbatim
- Offer <u>guidance</u> for working with materials of unknown hazard
- Promote consistency among the five nanocenters
- Does not preempt national, state or local regulations







### **Work Planning**



- Review all work with nanomaterials for EH&S concerns following an established safetyassessment process
  - —Develop a well defined description of the work
  - —Involve appropriate subject matter experts
    - Industrial hygiene
    - Fire protection (for reactive materials)
    - Waste management
  - —Consider hazards of precursors and equipment
  - —Consider potential hazard of nanomaterials captured on filters

### **Engineered Controls**



- Work that could generate an aerosol should be conducted in a enclosed, ventilated system such as fume hood, glove box or glove bag
  - —Alternatively, use close capture system
  - —Filter/scrub exhaust air where nanoparticles may be generated
  - —Do not recirculate exhaust air if possible
    - Avoid HEPA filtered stand alone hoods or biosafety cabinets if not exhausted to the outside
    - NEVER use laminar flow hoods (clean benches)
- Test and maintain these systems

#### **Administrative Controls**



- Develop and implement a chemical hygiene plan specific to the scope of activities
- Housekeeping
  - —Clean surfaces after each shift if contaminated
    - Consider reactivity of material when selecting method
    - Dedicated HEPA Vacuum
    - Wet wiping
- Work practices
  - —Keep materials in closed containers except when inside ventilated systems
  - —Minimize potential for aerosol and skin contact
  - —Use PPE when engineered controls not used

#### **Posting and Labeling**



- Post signs at entrance to work area warning of nanomaterials
- Label storage containers



#### COMMENTS:

Dispersible nanoscale materials may be handled in this lab



**Building 67 Rooms 1201** 









#### MINIMUM REQUIRED PERSONAL PROTECTIVE EQUIPMENT:

Eye protection required within delineated area surrounding fume hood

Carry eye protection at all times in other parts of lab

#### APPLICABLE FORMAL WORK AUTHORIZATION DOCUMENTS:

COMMENTS:

#### RESPONSIBLE INDIVIDUALS:

None

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 Work Cell #
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#### BUILDING AND FACILITY MANAGER:

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Rick Kelly	67-3205	(510) 486-4088	[510) 457-8452	(510) 537-8391

#### **Personal Protective Equipment**



- Wear PPE when failure of a single control could entail significant risk of exposure
  - Alternately, equip engineered controls with performance monitors
- Typical wet chemistry PPE when needed
  - Closed toe, low permeability shoes
  - Long pants without cuffs
  - Gauntlet gloves or gloves with sleeve extenders
  - Lab coats (consider notifying vendor)
  - Eye protection
- Respirators should be half mask
   P100 if used



### **Monitoring and Characterization**



- Minimally, use direct reading instrument to measure airborne nanoparticle level
- Perform more sophisticated air sampling
  - —Recommended method provided in appendix A
    - TSI 3007 Nanoparticle counter
    - GRIMM particle sizer
    - Filter collection with EM analysis
  - —Other alternatives
    - Size selective nanoparticle counters
    - Surface area counters







### **Worker Competency**



- Identify people potentially exposed to nanoparticles
  - —Registry
- Provide appropriate nanosafety training
  - —Also training for chemicals, PPE, waste, etc
- Provide awareness-level training to guests (users)
- Provide written procedural requirements to guests



#### **Medical Exams**



- Provide workers with "baseline" medical evaluations and nonspecific routine health monitoring program
  - -Worker
    - works with nanoparticles & may inhale them or get them on their skin, or
    - spends significant time in area where dispersible nanoparticle are handled, or
    - works on potentially contaminated equipment
- Provide immediate exam for people exposed in an "incident"
- Exempts non-resident people
  - —Guests, users



### **Waste Management**



- If <u>classified as hazardous</u> per 40 CFR or state regulations, dispose of waste using standard hazardous waste procedures
- If <u>not classified as hazardous</u>, send the waste to a RCRA permitted TSDF anyway
  - —Include instruction on how to dispose of material
- Do not permit nanomaterials to be shipped to researchers home institution for disposal



### **Spills**

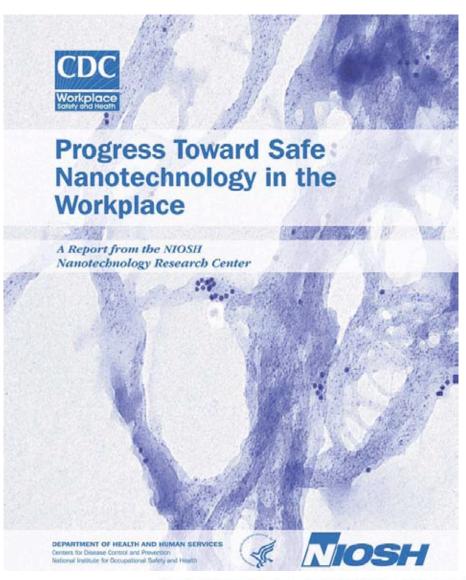


- Small spills cleaned up by lab personnel
- Large spills cleaned up by hazmat team
- Refer any people exposed in the incident for a medical review
- Clean up spill using wet methods/HEPA vacuuming
- Treat all clean up equipment as "contaminated"
- Dispose of waste appropriately



#### **More NIOSH Guidance 6/2007**





- Use standard engineering controls
  - Enclose source
  - Local exhaust
  - HEPA filters
- Administrative controls
  - Wet methods
  - Cleaning
  - Training
- PPE
  - HEPA filtered respirators work
- Summary of NIOSH research activities, partnerships, lit review

### **ASTM E 2535-07 (10/07)**





Designation: E 2535 - 07

#### Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings<sup>1</sup>

This standard is issued under the fixed designation E 2535; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

#### INTRODUCTION

Nanometer-scale particles are encountered in nature and in industry in a variety of forms and materials. Engineered nanoscale particles as a class comprise a range of materials differing in shape, size, and chemical composition, and represent a broad range of physical and chemical properties. Workers within some nanotechnology-related industries and operations have the potential to be exposed to these engineered nanoscale particles at levels exceeding ambient nanoscale particle concentrations through inhalation, dermal contact and ingestion when not contained on or within a matrix (unbound). Occupational health risks associated with manufacturing, processing and handling unbound nanoscale particles, agglomerates or aggregates of nanoscale particles are not yet clearly understood. Dominant exposure routes, potential exposure levels and any material hazard are expected to vary widely among particular nanoscale particle materials and handling contexts. Additional research is needed to understand the impact of these exposures on employee health and how best to devise appropriate exposure monitoring and control strategies. Until clearer understandings emerge, the limited evidence available suggests caution when potential exposures to unbound engineered nanoscale particles (UNP) may occur.

### **Key Features**



- Broad scope--R&D, manufacturing, other
- Applicable where there are no exposure standards, no robust risk information
- Applies to unbound engineered nanoparticles or their respirable agglomerates or aggregates
  - —Up to 10 µm aerodynamic size (unusual)
- The Control Principle: Minimize exposures to "As Low As Reasonably Practicable"
  - —NSRCs judged that we were already doing this but refused to refer to it as *ALARP*

### **Key Features**



#### Requires:

- —Formal written management policy
  - Materials characterization and safety data
  - Documentation of exposure and risk assessments
  - Engineering and other analyses
  - Work rules, SOPs, response plans
  - Training materials
  - Feedback process
  - Periodic review of program
- —Program manager
- —Training

### **ASTM–Key Features**



- Air sampling if possible
  - —Exposure limits—Starting points
    - ACGIH–Insoluble PNOS exposure <3 mg/m3 respirable
    - EPA Ambient Air Quality Standards PM2.5 35 μg/m3
    - NIOSH Nano TiO2 standard—0.1 mg/m3
    - Carbon Nanotubes—TLV for quartz 25 µg/m3

#### **ASTM-Exposure Control**



- Engineering controls work
  - —Isolation
  - —Fixation--use non-dusty techniques
  - —Waste minimization
  - —Local exhaust
  - —Containment (within room)
  - —HEPA filters

### **ASTM-Exposure Control**



- Administrative controls
  - —Housekeeping
  - -No compressed air, dry sweeping
  - —Wet Methods
  - —Decontaminatable surfaces
  - —Good hygiene
  - -Access controls
  - —Attention to process control, equipment commissioning
  - —Training
  - —Process control

#### **ASTM-Exposure Control**



- Medical surveillance—think about it!
- Consider non-routine activities—Maintenance, commissioning, decommissioning
- Control material transfer between containers
- Manage containers and storage
  - —Used containers
- Plan for waste handling
- Be prepared to responding to spills
- Use PPE as necessary
  - Make sure it will work for your nanoparticles
- Communicate the hazard–Signs and labels
  - —Identify the hazards
  - —Specify work locations
  - —Indicate methods to protect oneselve's
- MSDSs-get or prepare good ones!!

### ISO Technical Report 12885 (10/2008)



- Health and safety practices in occupational settings relevant to nanotechnologies
  - —Literature review
  - —Exposure assessment techniques
    - Air sampling
    - Dermal exposure assessment
  - —Risk assessment strategies
  - —Exposure control strategies
  - —Administrative controls
  - —Recordkeeping
  - —Waste management, fire and explosion control
  - —PPE

### ISO Technical Report 12885 (10/2008)



- Health surveillance
  - —Consider whenever there is exposure and a measurable biological indicator
  - —Establish individual baselines rather than relying on population "reference values"
  - —"Basic worker health monitoring program" is the minimum (lifted from NSRC guideline)
    - Maybe pulmonary, renal,m liver and hematopoietic system function testing, maybe not!

#### NIOSH Medical Surveillance Guide (2/2009)





### Current Intelligence Bulletin 60

Interim Guidance for Medical Screening and Hazard Surveillance for Workers Potentially Exposed to Engineered Nanoparticles

#### NIOSH Medical Guide (2/2009)



Currently there is insufficient scientific and medical evidence to recommend the specific medical screening of workers potentially exposed to engineered nanoparticles. Nonetheless, this lack of evidence does not preclude specific medical screening by employers interested in taking precautions beyond existing industrial hygiene measures. If nanoparticles are composed of a chemical or bulk material for which medical screening recommendations exist, these same screening recommendations would be applicable for workers exposed to engineered nanoparticles as well.

As research into the hazards of engineered nanoparticles continues, vigilant reassessment of available data is critical to determine whether specific medical screening is warranted for workers. In the interim, the following recommendations are provided for workplaces where workers may be exposed to engineered nanoparticles in the course of their work:

- Take prudent measures to control exposures to engineered nanoparticles.
- Conduct hazard surveillance as the basis for implementing controls.
- Continue use of established medical surveillance approaches.

#### NIOSH Medical Guide (2/2009)



- "No substantial link has been established between occupational exposures to engineered nanoparticles and adverse health effects."
- "...toxicological research to date is insufficient to recommend such (medical) *monitoring*, the appropriate triggers for it and components of it."
- Lack of information on sensitivity, specificity, predictive values of tests

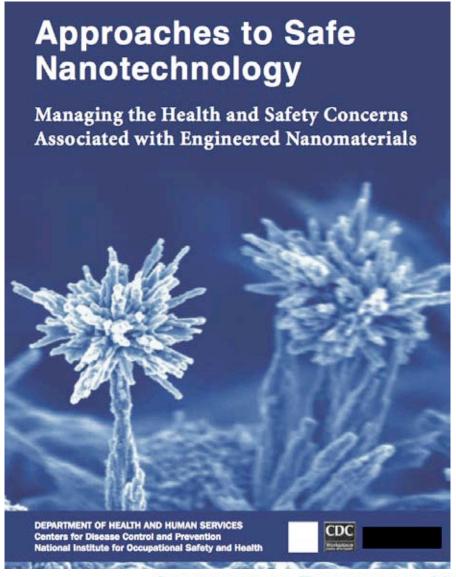
#### NIOSH Medical Guide (2/2009)



- "...insufficient information is now available to make any recommendations beyond hazard surveillance."
- "NIOSH continues to recommend occupational health surveillance as an important part of an effective risk management program."
- "...continue using established approaches to collect data that may be informative in the future about whether there is an increase in the frequency of adverse health events related to exposure to engineered nanoparticles".
- "Lack of evidence...should not stop employers who want to take additional precautions, including medical screening..."

### Newest NIOSH Guide (3/2009)





- Update of prior guidance
- Some good information
- Doesn't change a whole lot

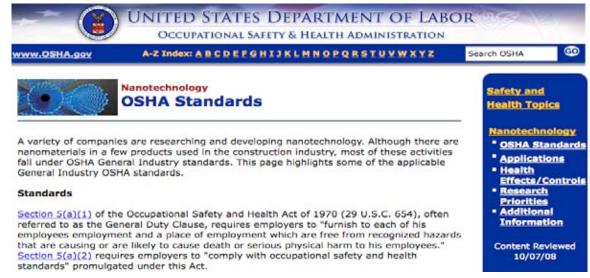
### **EPA CNT Rules (Pending)**



- "May present unreasonable risk to human health..."
- Requires full face respirators with N-100 filters for "manufacturers" of carbon nanotubes!
- Requires protective clothing and gloves!
- Read more:
  - —http://hs.environmentalexpert.com/resultEachPressRelease.aspx?cid =4280&codi=53524&lr=1

### **OSHA** (Cal and Federal)





Skij

GOV Welcome to the California
DEPARTMENT OF INDUSTRIAL RELATIONS

Return to: Industrial Relations Home

nanoparticle

Search Industrial Relations

Advanced Search Search Help

Your search - **nanoparticle** - did not match any documents. No pages were found containing **"nanoparticle"**.

#### Suggestions:

- Make sure all words are spelled correctly.
- · Try different keywords.
- Try more general keywords.

### New DOE 456.1 Policy (January 2009)



- DOE rule relating to nano work at DOE labs
- Failed process, flawed product
  - —Ignore unless you are a DOE contractor
  - —To be revised in Winter 2009-10, hopefully better product

### **Everybody is Working On This!**



#### **IRSST** publications

1-1

Best Practices Guide to Synthetic Nanoparticle Risk Management

Ostiguy, Claude; Roberge, Brigitte; Ménard, Luc; Endo, Charles-Anica Studies and Research Projects / Report R-599, Montréal, IRSST, 2009, 67 pages. Octor patient reports (4-403) Version française disponible : 8-586

Free download (526 Ko)



icles. Prepared jointly by the IRSST, CSST and NanoQuébec, this best practices guide proposes ynthesizing nanoparticles.

anoparticles is still limited. Among other things, the toxic effects related to the capacity of in certain organs and inside cells are only partially documented. While nanoparticles can be

#### FEATURE

Potential risks of nanomater and how to safely handle materials of uncertain toxicit

In the last few years, the number of research studies on the toxicity of different types of nanomaterials increased dramatically. These studies have suggested effects at the cellular level and in short-term anii tests. The effects seem depend on the base material of the nanoparticle, its size and structure, and substituents and coatings. Additional toxicology testing is being funded or planned by the Natio Nanotechnology Infrastructure Network and other research organizations in the US and in Euro Nanomaterials of uncertain toxicity can be handled using the same precautions currently used at universit to handle other materials of unknown toxicity: use of exhaust ventilation (such as fume hoods and vested enclosures) to prevent inhalation exposure during procedures that may release aerools or fibers and use of gloves to prevent dermal exposure. This article presents an overview of some of the major questions in nanotoxicology and also discusses the best practices that universities such as MIT and others are currently using to prevent exposure.

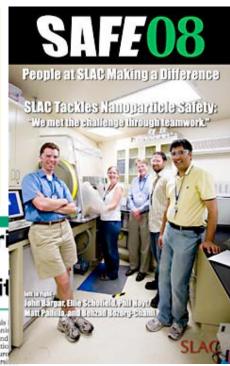
By Marilyn F. Hallock, Pam Greenley, Lou DiBerardinis, Dan Kallin

#### WHAT ARE NANOMATERIALS?

The focus of this article is engineered nanoparticles that are intentionally The focus of this article is engineered nanoparticles that are intentionally fabricated for their nanoscale properties.

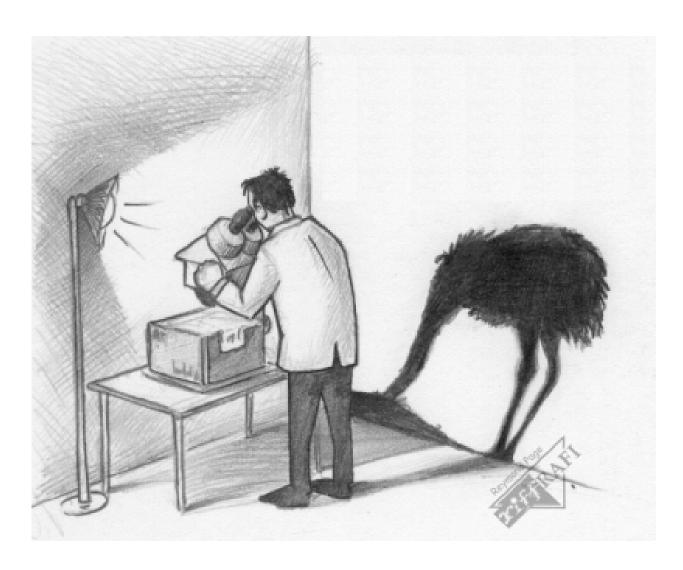
fabricated for their nanoscale proper-

Particles in the nanometer size range do occur both in nature and as an incidental byproduct of existing industrial processes. Nanosized particles are part of the range of atmospheric particles generated by natural events such as volcanic cruptions and forest fires. They also are part of the humes generated during welding, automobile exhaust, and other industrial combustion processes. One concern about small parcesses.



### **Questions?**





#### More stuff to look at



#### Universities & research center protocols

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#### **Still More**



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 Also ICON at http://icon.rice.edu/